

Notice of Allowability

Application No.

10/758,247

Examiner

Daniel M. Sullivan

Applicant(s)

DWEK ET AL.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Paper filed 23 August 2007.
2. ☒ The allowed claim(s) is/are 1,14,15 and 40-42.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 8/07
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Sarah J. Fashena on 23 October 2007.

The application has been amended as follows:

In the specification

Amend page 1, paragraph 2 as follows:

-- 2. This application is a continuation of co-pending Application Serial No. 10/042,527 filed October 19, 2001, now abandoned, which is, in turn, a continuation of PCT/GB00/101560 filed April 20, 2000, which in turn, claims priority from GB Application No. 9909066.4 filed April 20, 1999. All of the afore noted applications are herein specifically incorporated by reference, and applicants claim the benefits of 35 U.S.C. § 120 as to said U.S. and PCT applications, and the benefits of 35 U.S.C. § 119 as to said GB application.--

In the claims

Cancel claims 4-8, 12, 13 and 16-39.

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Amend claims 1, 15 and 40-42 as follows:

1. (currently amended). A method for reducing accumulation of glucosylceramide-containing glycolipids in a patient afflicted with a glycolipid storage-related disorder, comprising administering to said patient afflicted with a glycolipid storage-related disorder an inhibitor of glycolipid synthesis in combination with an agent capable of increasing the rate of glycolipid degradation, wherein said inhibitor of glycolipid synthesis is N-butyldeoxynojirimycin (NB-DNJ) and is administered in an amount effective to reduce accumulation of glucosylceramide-containing glycolipids in said patient, and the agent capable of increasing the rate of glycolipid degradation is glucocerebrosidase.

15. (currently amended). The method of claim 1, wherein the inhibitor of glycolipid synthesis and the agent capable of increasing the rate of glycolipid degradation are given to said patient afflicted with a glycolipid storage-related disorder simultaneously, sequentially, or separately.

40. (currently amended). A method for augmenting glucocerebrosidase activity in a patient afflicted with a glycolipid storage-related disorder, comprising administering to said patient afflicted with a glycolipid storage-related disorder an inhibitor of glycolipid synthesis in combination with an agent capable of increasing the rate of glycolipid degradation, wherein the agent capable of increasing the rate of glycolipid degradation is glucocerebrosidase, and wherein said inhibitor of glycolipid synthesis is N-butyldeoxynojirimycin (NB-DNJ) and is administered in an amount effective to augment glucocerebrosidase activity in said patient.

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41. (currently amended). A method for increasing the rate of glycolipid degradation in a patient afflicted with a glycolipid storage-related disorder, comprising administering to said patient afflicted with a glycolipid storage-related disorder an inhibitor of glycolipid synthesis in combination with an agent capable of increasing the rate of glycolipid degradation, wherein the agent capable of increasing the rate of glycolipid degradation is glucocerebrosidase and wherein the inhibitor of glycolipid synthesis is N-butyldeoxynojirimycin (NB-DNJ) and is administered in an amount effective to increase the rate of glycolipid degradation in said patient.

42. (currently amended). A method for improving survival of a patient afflicted with a glycolipid storage-related disorder, comprising administering to said patient afflicted with a glycolipid storage-related disorder an inhibitor of glycolipid synthesis in combination with an agent capable of increasing the rate of glycolipid degradation, wherein said inhibitor of glycolipid synthesis is N-butyldeoxynojirimycin (NB-DNJ) and is administered in an amount effective to improve survival of said patient, and the agent capable of increasing the rate of glycolipid degradation is glucocerebrosidase.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779.

The examiner can normally be reached on Monday through Friday 6:30-3:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel M. Sullivan/
Primary Examiner
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